Lilly

Eli Lilly and Company

US Regulatory Affairs
1700 Rockville Pike, Suite 450
Rockville, Maryland 20852
301 770 0788
Fax 301 881 6317

September 17, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1663; Proposed Rule, Investigational New Drugs: Export Requirements for Unapproved New Drug Products; 67 Federal Register 41642 (June 19, 2002)

Dear Sir/Madam:

The following comments on the above-proposed rule are submitted on behalf of Eli Lilly and Company. Eli Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives. In 2001, we invested $2.2 billion in Research and Development efforts for new medicines.

Eli Lilly supports this proposed rule and appreciates the effort by the Agency to simplify the existing requirement for export of investigational new drugs, especially considering the upward trend in the number of days required to receive export waivers over the past few years. In preparation of the final rule, the following comments are submitted for Agency consideration.

As globalization of the pharmaceutical industry continues, there has been an increasing number of export requests. Over the past four years, there has been an increased burden on the agency, resulting in delay of export requests without any concomitant benefit to the public health. We believe the proposed rule streamlines the export of clinical trial material in a way that is consistent with FDA's overall approach to regulation, while maintaining the existing standards.

00N-1663 C 3

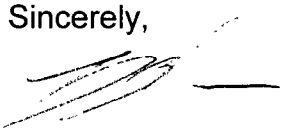
In the FR notice regarding the proposed rule, FDA invites comments on whether the Agency should make available information on clinical trials involving investigational new drugs exported under the 312 program. Clearly, the FDA is required to provide information on studies conducted under an IND with certain investigational drugs, according to Section 113 of the Food and Drug Administration Modernization Act of 1997. However, for studies with exported drugs not conducted under an IND, it is our belief that FDA has no legal basis upon which to collect or disclose information. Moreover, it would impose a significant reporting burden upon sponsors with no corresponding value to the American population. The law is intended to provide Americans with beneficial information, such as ongoing clinical studies or newly approved treatments with available safety and efficacy data. However, we believe that studies with exported drugs not conducted under an IND do not provide this information. Our position, rather, is that only trials taking place at research sites in the US are required to be posted to the data bank. This position complies with Congressional intent. Finally, since the trials will not be taking place in the US, any export requirements for clinical trial material should not be bound by the provision of law.

Regarding section 802 (c) of the FDA Export Reform and Enhancement Act of 1996 (FEREA), the FDA states that its interpretation permits investigational drugs to be sent to principal investigators in a listed country for use by him or her in an unlisted country. Accordingly, this is only permitted if the studies conducted in the unlisted country are done in accordance with the laws governing both the listed and the unlisted countries. In our opinion, the above interpretation is equivalent to an acceptance of transshipment. However, under FEREA and the proposed regulation, the FDA has stated clearly that transshipment is prohibited. Although the Agency states that different interpretations of the law have occurred in the past and that other current interpretations are welcome, the above-proposed rule does not adequately address this potential interpretive discrepancy. Consequently, we believe that the Proposed Rule should address this point more conclusively. In reality, once an investigational drug is exported from a listed country, the ability of an investigator to control drug movement, storage, and utilization may be very limited, even with the support of the laws of the land. This is not a question of how conscientious the investigator may be but rather an issue of significant risks and unrealistic expectations. Expecting an investigator to require and enforce laws, regulations, and practices of the listed country in the unlisted country is truly unrealistic, even if there are no contraindications between them. Moreover, the investigator, sponsor, and most importantly, the patient, are exposed to significant risks through this uncontrollable process. Eli Lilly proposes that (a) transshipment of drugs in listed countries to unlisted countries should not be permitted; (b) exports of drugs from the United States to unlisted countries should be allowed under the FDA proposed rule; and (c) FDA should work diligently to approve unlisted countries, and add them to the listed countries.

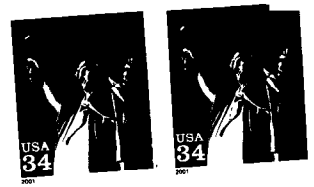
Finally, the proposed section 312.110(b)(4) requires that "the drug is promoted in accordance with the labeling." Since the proposed rule limits exports to investigational new drugs, we question the need for the above requirement. Investigational new drugs are not the subject of promotion; therefore, this requirement is unnecessary.

Eli Lilly and Company thanks the FDA for the opportunity to comment on this proposed rule. Furthermore, we are prepared to respond to any question the Agency might have regarding our response.

Sincerely,



Thomas L. Copmann, Ph.D.
Senior Director, US Regulatory Affairs



Do Not Forward / Address Correction Requested / Return Postage Guaranteed

Lilly

Eli Lilly and Company
US Regulatory Affairs
1700 Rockville Pike, Suite 450
Rockville, Maryland 20852

FIRST CLASS

Ship To:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

00 NK 9704

Comments:

Docket No. 00N-1663; Proposed Rule,
Investigational New Drugs: Export Requirements
for Unapproved New Drug Products; 67 Federal
Register 41642 (June 19, 2002)